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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,752	03/26/2001	Olga Bandman	PF-0559 USN	7326

7590 12/17/2003

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EXAMINER	
PAK, YONG D	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,752	BANDMAN ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-45* is/are pending in the application.

4a) Of the above claim(s) *32-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23 and 26-31* is/are rejected.

7)☒ Claim(s) *24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The preliminary amendment filed on September 29, 2003, canceling claims 1-20 and adding claims 21-45, has been entered.

Claims 21-45 are pending.

Election/Restrictions

Applicant's election with traverse of Group III is acknowledged. The traversal is on the ground(s) that Group I and Group III shares a special technical feature because the prior art relied on in the Restriction Requirement was not publically available before the priority date of the instant application. This is found persuasive. However, Group I and Group III lacks a special technical feature because for a DNA and protein group to share a special technical feature, claims drawn to the DNA must be DNA sequences that encode the structure of the protein in the claims drawn to the protein (see PCT administrative instructions Example 17). In the instant invention, the DNA and proteins claims to not correspond to each other in that claims are drawn to DNA encoding SEQ ID NO:1 and other unrelated polypeptides. Therefore, the technical feature linking Groups I and III is lacking.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-22 and 32-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Notice of Possible Rejoinder: The Examiner notes that if claims 23-31 are found directed to an allowable product, then claims 32-34 and 39-42, which are directed to the process of making or using the patentable product, respectively, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also MPEP 821.04, *In re Ochiai,* and *In re Brouwer*). Since process claims 32-34 and 39-42 would be rejoined and fully examined for patentability under 37 CFR 1.104, applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 29, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claims 23-30 are objected to as being dependent upon a non-elected base claim, and should be rewritten in independent form including all of the limitations of the base claim and any intervening claims. The claims have been interpreted to include all the limitations of its base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23 and 26-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 23 and 26-31 are drawn to a DNA molecule encoding a polypeptide with no limitations to the function of the encoded polypeptides. Therefore, the claims are drawn to a large variable genus of polynucleotides encoding polypeptides having unknown activity or inactive variants. The specification does not describe the function of all the polypeptide sequences derived or modified from SEQ ID NO:1 and therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims. Therefore, applicants fail to describe representative species by identifying characteristics or functional characteristics other than being fragments of SEQ ID NO:1.

The claims are also drawn to DNA fragments comprising only 60 nucleotides of SEQ ID NO:3 and DNA molecules encoding a polypeptide comprising only 15 amino acids of SEQ ID NO:1. A description of only 45-60 nucleic acids, which represent less than 5% of the whole structure of the DNA molecule, amount to insufficient description of the structure of the DNA molecules in these claims. Therefore, these claims are drawn to a large variable genus of DNA molecules encoding polypeptides having

unknown activity or inactive variants with an insufficient limitation on structure. Therefore, the specification fails to describe representative species by any identifying structural characteristics or functionality other than comprising of small fragments of DNA encoding SEQ ID NO:1.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 23 and 26-31.

Claim 23 and 26-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA encoding the polypeptide of SEQ ID NO:1, does not reasonably provide enablement for DNA molecules encoding dehydrogenase that is not homologous to SEQ ID NO:11. The specification also does not reasonably provide enablement for polynucleotides encoding polynucleotide having unknown function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in

the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to polynucleotides encoding polypeptides having unknown function. The claims broadly encompass not only short-chain alcohol dehydrogenase SCAD) genes, but any polynucleotides comprising of fragments of polynucleotides encoding SEQ ID NO:1. The claims also encompass molecules having very low structural similarity to DNA encoding SEQ ID NO:1 that exhibit SCAD activity and proteins of unknown functionality. The structural limitations are as follows: only 45-60 nucleic acids, which represent 5% of the whole structure of SEQ ID NO:3. Therefore, these claims encompass polynucleotides encoding a dehydrogenase having structures with low homology to SEQ ID NO:1. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The specification does teach how to make variants of polynucleotides encoding SEQ ID NO:1. However, the function of a polypeptide can not be predicted from its structure and the specification does not teach how to use polypeptides with unknown function. The quantity of experimentation in this area is extremely large since there is significant variability in the activity of the polynucleotides in the claims. It would require significant study to identify the actual function of the encoded polypeptides and identifying a use for the polypeptide would be an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The art is extremely unpredictable with regard to protein function in the absence of realizable information regarding its activity. Even very similar proteins may have every different functions. In the current case, where no specific information is know regarding the function, it is entirely unpredictable what function and activity will be found for the protein. The prior art does not resolve this ambiguity, since no prior art activity is identified for the encoded polypeptides.

Further, despite knowledge in the art for isolating polynucleotides, the specification fails to provide guidance regarding which amino acids of SEQ ID NO:1 are required to impart a polypeptide as a dehydrogenase. While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity are limited in any protein and the result of such modifications is unpredictable.

The specification, which places weak limitation on the structure of the polypeptides as discussed above, does not support the broad scope of the claims because the specification does **not** establish: (A) regions of the SCAD structure which may be modified without effecting dehydrogenase activity; (B) the general tolerance of to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Therefore, one of ordinary skill would require guidance in order to use polynucleotides encoding polypeptides having unknown function in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 and 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 23, which ultimately depend from claim 21, the phrases "biologically active fragment" and "immunogenic fragment" are unclear because the claim can refer to many polypeptides with different biological and immunogenic activities. Therefore, the scope of the polynucleotides in the claims is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonaldo et al.

Bonaldo et al. (form PTO-892) teach a polynucleotide that comprises of at least 60 contiguous nucleotides of SEQ ID NO:3 (see sequence alignment). Therefore, the teaching of Bonaldo et al. anticipates claims 23 and 31.

Claims 23 and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gabrielli et al.

Bonaldo et al. (form PTO-1449) teach a polynucleotide comprising a fragment of a SCAD protein (page 474). Bonaldo et al. also teach a vector comprising said polynucleotide, cell transformed with said vector and a method of producing said protein. Therefore, the teaching of Bonaldo et al. anticipates claims 23 and 26-28.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong D. Pak
Patent Examiner

December 10, 2003

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SUPERVISORY PATENT EXAMINER
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